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|---|-------------|----------------------|---------------------|------------------|
| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 09/870,009 | 05/30/2001 | Hisashi Kashima | JP920000069US1 | 8419 |
| 21254 | 7590 | 09/15/2004 | EXAMINER | |
| MCGINN & GIBB, PLLC 8321 OLD COURTHOUSE ROAD SUITE 200 VIENNA, VA 22182-3817 | | | SMITH, CAROLYN L | |
| | | ART UNIT | PAPER NUMBER | |
| | | 1631 | | |

DATE MAILED: 09/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------|------------------------|---------------------|
| Advisory Action | Application No. | Applicant(s) |
| | 09/870,009 | KASHIMA ET AL. |
| | Examiner | Art Unit |
| | Carolyn L Smith | 1631 |

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 01 September 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) The period for reply expires 3 months from the mailing date of the final rejection.
- b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. The proposed amendment(s) will not be entered because:
 - (a) they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) they raise the issue of new matter (see Note below);
 - (c) they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. Applicant's reply has overcome the following rejection(s): _____.
4. Newly proposed or amended claim(s) ____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. The a) affidavit, b) exhibit, or c) request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
6. The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. For purposes of Appeal, the proposed amendment(s) a) will not be entered or b) will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 5,8-12 and 15-30.

Claim(s) withdrawn from consideration: _____.

8. The drawing correction filed on ____ is a) approved or b) disapproved by the Examiner.

9. Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). 2 pages.

10. Other: Attachment: 1 pg. of PTO-1449

Continuation of 2. NOTE: The added limitations in proposed amended claims 5, 8, 11, 12, and 15 are new issues that would require further consideration and/or search. Therefore, all of the rejections stated in the FINAL rejection, mailed 6/8/04, are maintained.

The information disclosure statement (IDS), filed 5/17/04, fails to comply with the provisions of 37 CFR 1.97, 1.98, and MPEP § 609, because references (Hara and Nakayama, on page 1 of the IDS) are in a foreign language. The abstract of the Katsumata et al. (Japanese Journal of Medical Procedures) reference has already been considered in a previous IDS. The remainder of the reference was not considered as it is in a foreign language. The Japanese office action with English translation has been looked at but has not been officially considered as it does not have a publication date. The Ministry of Agriculture and Matsubara references were not considered as they are in a foreign language. A translation of these references is needed if Applicants want these references to be considered. These references have been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609, C(1).

35 USC 101 rejection

This rejection is maintained due to the nonentry of the after final amendment. If the proposed amendment had been entered, this rejection would have been removed.

35 USC 112, 2nd rejection

All of the 35 USC 112, 2nd rejections are maintained due to the nonentry of the after final amendment. If the proposed amendment had been entered, the rejection of claim 5 regarding "a portion, other than said gene portion, including no genetic information" would have been maintained, while the remaining 112, 2nd rejections would have been withdrawn. Applicants state Examiner must use the definition of the term "genetic information" which is provided in the Application. Applicants state their definition of this phrase is on page 13, lines 3-6. This so-called definition is found unpersuasive as it does not clearly set forth the definition explicitly and with reasonable clarity, deliberateness and precision (MPEP 2111.01). When there is no explicit definition in the specification, the Examiner is instructed to look to the claims themselves and the context of the surrounding words, dictionaries, encyclopedias, treatises, and the prior art. The online Merriam-Webster dictionary defines "genetic" as "of or relating to genetics". The dictionary defines "genetics" as the genetic makeup and phenomena of an organism. The dictionary defines "information" as "knowledge obtained from investigation, study, or instruction". This phrase "genetic information" therefore can be reasonably and broadly interpreted to include all DNA by the mere presence of nucleotides which are encompassed by the phrase.

35 USC 102 rejection

This rejection is maintained due to the nonentry of the after final amendment. If the proposed amendment had been entered, a further search and consideration would be required to determine if the rejection would have been maintained due to the added phrase limitation of "which is not naturally occurring in said DNA and ". Applicant states the Dollinger reference is overwhelmingly unrelated to the claimed invention. This statement was found unpersuasive for the previous set of claims (pre-FINAL) as they were broadly written to encompass the Dollinger reference. Applicants state Dollinger has nothing to do with DNA. This statement is found unpersuasive as Dollinger's recitation of nucleic acids is clearly a representation of DNA. The online Merriam-Webster dictionary defines DNA as "any of various nucleic acids..." As stated above, a further search and consideration would be required to determine if the proposed amendments would still be rejected by prior art.

Ardin H. Marschel 9/11/04
ARDIN H. MARSCHEL
PRIMARY EXAMINER